K082967

SECTION 16: SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

MAR 2 6 2009

16.1 SUBMITTER INFORMATION

a. Company Name:	Medical Positioning, Inc.
b. Company Address:	1717 Washington Kansas City, MO 64108
c. Company Phone: Company Facsimile:	(816) 474-1555 (816) 474-7755
d. Contact Person:	Michael G. Falbo, Sr. Vice President, Product Development
e. Date Summary Prepared:	September 30, 2008

16.2. DEVICE IDENTIFICATION

a. Trade/Proprietary Name:	Mortara Stress Echo™ Bed
b. Classification Name:	Electrocardiograph 21 CFR 870.2340

16.3 IDENTIFICATION OF PREDICATE DEVICE

Company	Device	510(k) No.	Date Cleared
Medical Positioning	Vertex System	K002822	01/30/01
Medical Positioning	Q-Stress Echo Bed	K021171	05/08/02
Mortara Instruments	Mortara X-Scribe II	K022618	09/06/02

16.4 DEVICE DESCRIPTION

The Mortara Stress Echo™ Bed is a complete integrated stress echocardiography system. The Mortara Stress Echo™ Bed combines the Stress Echo Bed / Table with an electrocardiograph. The Stress Echo Bed provides an exercise source that delivers programmable, controlled variable resistance, while the ECG provides the patient monitoring and recording. Several models of the Stress Echo Bed/Table are available with features that include height adjustability, Trendelenburg, dual, lateral tilt, and computer controllers.

16.5 SUBSTANTIAL EQUIVALENCE

The Mortara Stress Echo™ Bed is substantially equivalent to the Vertex System and the Q-Stress Echo™ currently in commercial distribution by Medical Positioning. The Mortara Stress Echo™ Bed and the predicate devices incorporate the same Stress Echo™ Bed and an electrocardiograph. The Mortara Stress Echo™ Bed incorporates the Mortara X-Scribe II electrocardiograph manufactured by Mortara Instruments.

The fundamental technical characteristics of the Mortara Stress Echo™ Bed and the Vertex System and Q-Stress Echo Bed are equivalent and are listed on the comparison charts provided in this 510(k) submission. The Mortara Stress Echo™ Bed and the predicate devices function by providing the user with an integrated exercise source and electrocardiograph for use during cardiovascular monitoring.

16.6 INTENDED USE

The Mortara Stress Echo™ Bed is intended for use in stress echocardiography examination. The Mortara Stress Echo™ Bed provides an exercise source that delivers programmable, controlled variable resistance.

The Mortara Stress Echo™ Bed incorporates an electrocardiograph that records either normal conditions or patterns of arrhythmia and/or rate abnormalities in

patients. In addition, the Mortara Stress Echo™ Bed provides "QRS" complex to a cardiac ultrasound device to be used to capture images (heart beats), either digitally or on videotape, such that each image begins at the time systole begins.

16.7 TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the Mortara Stress Echo™ Bed are equivalent to those of the Vertex System and the Q-Stress Echo™ Bed. The Mortara Stress Echo™ Bed utilizes a supine bicycle for the exercise source. Preprogrammed exercise protocols are run for purposes of electrocardiographic monitoring. The ECG used in the Mortara Stress Echo™ Bed is the Mortara X-Scribe II electrocardiograph that has been cleared for commercial distribution under K022618. ECG reports, trends, averages and ST segments are printed by the Mortara Stress Echo™ Bed. The Mortara Stress Echo™ Bed is connected using standard patient electrodes and leads that are not included in the system.

16.8 PERFORMANCE DATA

The Mortara Stress Echo™ Bed was subjected to performance bench testing. Physical performance studies and software evaluation were conducted to verify that the Mortara Stress Echo™ Bed performed as intended.

16.9 CONCLUSIONS

This notification contains all information required by 21 CFR 807.87. The Mortara Stress Echo™ Bed was found to perform as intended during verification and validation testing. The Mortara Stress Echo™ Bed is substantially equivalent to the current Vertex System and the Q-Stress Echo™ Bed in commercial distribution. The Mortara Stress Echo™ Bed is intended for use in stress echocardiography examination. The Mortara Stress Echo™ Bed provides an exercise source that delivers programmable, controlled variable resistance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 6 2009

Medical Positioning, Inc.
c/o Ms. Carol White
Consultant
21521 Hummingbird St.
Trabuco Canyon, CA 92679

Re: K082967
Trade Name: M-Stress Echo Bed
Regulation Number: 21 CFR 870. 2340
Regulation Name: Electrocariograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: February 23, 2009
Received: March 2, 2009

Dear Ms. White:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at 240-276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082967

Device Name: M-Stress Echo Bed™

Indications For Use: The M-Stress Echo™ Bed is intended for use in stress echocardiography examination. The M-Stress Echo™ Bed provides an exercise source that delivers programmable, controlled variable resistance.

The M-Stress Echo™ Bed incorporates an electrocardiograph that records either normal conditions or patterns of arrhythmia and/or rate abnormalities in patients. In addition, the stress echo workstation provides "QRS" complex to a cardiac ultrasound device to be used to capture images (heart beats), either digitally or on videotape, such that each image begins at the time systole begins.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K082967